JEFFREY BOSSERT CLARK
Acting Assistant Attorney General
DANIEL J. FEITH
Deputy Assistant Attorney General
GUSTAV W. EYLER
Director
HILARY K. PERKINS
Assistant Director
JONATHAN E. AMGOTT (DCBN 1031947)
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044-0386
Telephone: 202-532-5025
Facsimile: 202-514-8742
E-mail: Jonathan.E.Amgott@usdoj.gov
Attorneys for Federal Defendants
ALEX AZAR, STEPHEN HAHN, and
U.S. FOOD AND DRUG ADMIN.

THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

ANIMAL LEGAL DEFENSE FUND, FOOD & WATER WATCH, and FOOD ANIMAL CONCERNS TRUST,

Plaintiffs,

v.

ALEX AZAR, Secretary of the United States Department of Health and Human Services; STEPHEN HAHN, Commissioner of the United States Food and Drug Administration; and UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendants,

and

ELANCO ANIMAL HEALTH,

Intervenor-Defendant.

No. 3:20-CV-03703-RS

FEDERAL DEFENDANTS' NOTICE OF MOTION AND MOTION TO DISMISS FIRST AMENDED COMPLAINT

Hearing Date: Thursday, January 14, 2021
Hearing Time: 1:30 p.m.
Courtroom: 3

Hon. Richard Seeborg

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NOTICE OF MOTION AND MOTION TO DISMISS

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on Thursday, January 14, 2021, at 1:30 p.m., or as soon thereafter as they may be heard in San Francisco Courthouse, Courtroom 3 (17th Floor), Defendants Alex Azar, Stephen Hahn, and the United States Food and Drug Administration ("FDA," and collectively, "Federal Defendants"), by and through counsel, will and hereby do move to dismiss this action, filed on June 4, 2020, by Plaintiffs Animal Legal Defense Fund ("ALDF"), Food & Water Watch ("FWW"), and Food Animal Concerns Trust ("FACT") (collectively, "Plaintiffs"), for lack of Article III standing, pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure. Defendants' Motion is based on this Notice, the Points and Authorities incorporated herein, any matters for which the Court may take judicial notice, and any written and oral argument and authorities that are presented at or before the hearing on this Motion.

RELIEF SOUGHT

Defendants seek an order dismissing the First Amended Complaint (hereinafter, "Amended Complaint") under Rule 12(b)(1) because Plaintiffs have not established organizational standing, nor do they show associational standing through their members, who lack an injury in fact that is fairly traceable to Defendants' action nor is it likely redressable by a ruling in their favor.

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF FEDERAL DEFENDANTS' MOTION TO DISMISS THE FIRST AMENDED COMPLAINT

INTRODUCTION

Plaintiff organizations ALDF, FWW, and FACT ask this Court to vacate FDA's approval of the new animal drug Experior, which is approved to reduce ammonia gas emissions from cattle. Experior belongs to a subtype of a broader category of drugs called "beta-agonists" that facilitate increased industrial meat production. Plaintiffs allege that beta-agonists inflict harmful collateral effects on cows, humans, and the environment. Invoking these concerns, Plaintiffs claim that FDA's approval of Experior violated the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, the National Environmental Policy Act ("NEPA"), 42 U.S.C. § 4321 *et seq.*, and the Administrative Procedure Act ("APA"), 5 U.S.C. § 551, *et seq*. But Plaintiffs lack Article III standing to bring this suit, and their claims

should therefore be dismissed.

The first deficiency fatal to Plaintiffs' action is the dearth of a constitutional injury in fact, either to Plaintiffs or to their members. Because Plaintiffs have not alleged that they diverted their resources to address their asserted harms, they have not established organizational standing. *See, e.g.*, *Smith v. Pac. Props. & Dev. Corp.*, 358 F.3d 1097, 1101, 1105 (9th Cir. 2004). Nor have Plaintiffs established associational standing through their members, because those members have not suffered harms that are both concrete and particularized, and actual or imminent. *See, e.g.*, *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 342–43 (1977). All of Plaintiffs' alleged harms fall short of the "certainly impending" or "substantial risk" threshold. *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409, 414 n.5 (2013)).

Even if the Amended Complaint made out a legally cognizable injury (it does not), Plaintiffs are unable to establish causation because they have not shown that any of the purported harms are fairly traceable to FDA's approval of Experior. *See Tyler v. Cuomo*, 236 F.3d 1124, 1131–32 (9th Cir. 2000). Instead, the alleged harms to Plaintiffs' members are caused by the practices of industrial farms, by other drugs used on food-producing cattle, or by the decisions of independent third parties, including feedlot operators, or of Plaintiffs' members themselves. (*See, e.g.*, Am. Compl. ¶¶ 22, 63–75, 91–120.)

Yet even if the Court were to reach the third element, Plaintiffs still do not satisfy the constitutional minimum to bring this case. They have not shown—beyond mere speculation—that any harm fairly traceable to FDA's approval of Experior is likely redressable by this Court. *See Tyler*, 236 F.3d at 1131–32. Plaintiffs do not allege that withdrawal of Experior's approval will lead to fewer industrial farms or reduce the use of similar drugs. Indeed, they do not allege that it would have any impact on the decisions of third parties concerning the feedlot industry and other beta-agonists. Nor could that withdrawal remedy precautions that Plaintiffs' members themselves may have already taken. Plaintiffs have therefore not shown that the relief they seek will remedy their alleged injuries.

For these reasons, and as further explained below, the Court should grant Federal Defendants' Motion and dismiss Plaintiffs' claims.

STATEMENT OF ISSUES TO BE DECIDED

Whether Plaintiffs failed to establish organizational standing or associational standing through their members, thereby requiring dismissal of the Amended Complaint for lack of Article III standing under Fed. R. Civ. P. 12(b)(1).

BACKGROUND

On November 6, 2018, FDA approved the new animal drug Experior (lubabegron Type A medicated article), manufactured by Elanco, US, Inc. ("Elanco") (First Amended Complaint ("Am. Compl."), ECF No. 30, ¶¶ 1–2.) Experior has been shown to lower ammonia gas emissions in cattle fed in confinement for slaughter for the last 14-91 days on feed. (*See id.* ¶ 1.) Experior is classified as an adrenergic agonist/antagonist, which is a subtype of a broader category of drugs known as beta-adrenergic agonist/antagonists. (*See id.* ¶¶ 3, 63.) Experior marks the first new animal drug that FDA's Center for Veterinary Medicine has approved that activates from the beta-3 receptor ("beta-3") subtype and the first new animal drug approved to reduce gas emissions from an animal or its waste. (*See id.* ¶ 123.)

On December 6, 2018, Plaintiff ALDF sought a stay of Experior's approval by submitting a Petition for Stay of Action under 21 C.F.R. § 10.35 ("Petition"). (*See* Am. Compl. ¶¶ 10, 125.) The Petition alleged that FDA failed to sufficiently analyze Experior's environmental impact, did not consider alternatives to Experior's approval, and failed to prepare an Environmental Impact Statement ("EIS") addressing the effects Experior may have on animals, humans, and the environment. (*Id.* ¶ 9.) The Petition requested that FDA stay Experior's approval until the agency addressed ALDF's concerns. (*See id.* ¶¶ 9, 10, 125–26.)

FDA responded to ALDF's Petition on May 20, 2019 ("Response") by denying ALDF's request to stay the approval. (*See* Am. Compl. ¶¶ 11, 128–30.) FDA's Response addressed each point raised in the Petition and concluded that none of ALDF's arguments established any basis recognized by statute or regulation for a stay. (*See id.*)

On June 4, 2020, Plaintiffs filed suit, asking this Court to, *inter alia*, "[v]acate FDA's decision to approve Experior." (Compl., ECF No. 1, at 34, ¶ 3.) Plaintiffs' Amended Complaint filed on September 29, 2020, asserts claims under the FDCA, NEPA, and the APA. (*See* Am. Compl. at 35–38.) In addition

to requesting vacatur of the approval, Plaintiffs pursue declaratory and injunctive relief that includes "enjoining the use of Experior" until, in their view, FDA's approval process "complies" with those three statutes. (*Id.* at 38, Request for Relief ¶ 4.) Elanco has been permitted to join this case as an Intervenor-Defendant. (ECF No. 25.) Federal Defendants now move to dismiss this action in its entirety because Plaintiffs lack Article III standing.

LEGAL STANDARD

Federal Defendants challenge the sufficiency of the jurisdictional allegations in the Amended Complaint under Federal Rule of Civil Procedure 12(b)(1). *See Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004). Although a court may "assume [a plaintiff's] allegations to be true and draw all reasonable inferences in [its] favor," *Wolfe v. Strankman*, 392 F.3d 358, 362 (9th Cir. 2004), "plaintiff, as the party invoking federal jurisdiction, bears the burden of establishing the[] elements" of standing, *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). "Where, as here, a case is at the pleading stage, the plaintiff must 'clearly . . . allege facts demonstrating' each element" of standing to secure this Court's jurisdiction. *Id.* (quoting *Warth v. Seldin*, 422 U.S. 490, 518 (1975)). "[W]hen considering a motion to dismiss pursuant to Rule 12(b)(1) the district court is not restricted to the face of the pleadings, but may review any evidence, such as affidavits and testimony, to resolve factual disputes concerning the existence of jurisdiction." *Gordon v. United States*, 739 F. App'x 408, 411 (9th Cir. 2018) (quoting *McCarthy v. United States*, 850 F.2d 558, 560 (9th Cir. 1988) (alteration in original)).

ARGUMENT

This matter fails to satisfy minimum constitutional requirements for a federal case. Rooted in Article III's limitation of judicial power to cases and controversies, the standing "doctrine limits the category of litigants empowered to maintain a lawsuit in federal court to seek redress for a legal wrong." *Spokeo*, 136 S. Ct. at 1547. A plaintiff must show that it has: "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Id.* That showing must be made for "each claim" asserted, *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006), and "separately for each form of relief sought," *Friends of Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 185 (2000).

Organizational plaintiffs may establish standing in one of two ways: (1) directly, by demonstrating that the organizations themselves satisfy each element of the standing inquiry; or (2) by association, through one or more of their members who can meet the standing elements. *See Havens Realty Corp. v. Coleman*, 455 U.S. 363, 378–79 (1982); *see also Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 260–64 (1977).

Where, as here, plaintiffs are not themselves "the object" of a challenged government action, standing is "substantially more difficult to establish." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 562 (1992). In these instances, independent third parties attenuate the causal chain and undermine the court's ability to furnish redress. *Id.*

This is a paradigmatic case of failure to establish standing. The organizations not only fail to demonstrate cognizable injury, but also fail to show that the government action caused their alleged harms or that such harms would be redressed by this Court. Because Plaintiffs have not discharged their burden, the Court should dismiss this case for lack of jurisdiction.

I. Neither Plaintiffs Nor Their Members Have Suffered An Injury In Fact.

A. Plaintiffs Do Not Have Organizational Standing Because The Organizations Have Not Established Their Own Injury In Fact.

An organization may assert injury in fact on its own behalf if it alleges: "(1) frustration of its organizational mission; and (2) diversion of its resources" to combat the defendant's actions. *Pac. Props.*, 358 F.3d at 1101, 1105. This standard requires a showing "that the defendant's actions run counter to the organization's purpose, that the organization seeks broad relief against the defendant's actions, and that granting relief would allow the organization to redirect resources currently spent combating the specific challenged conduct to other activities that would advance its mission." *Rodriguez v. City of San Jose*, 930 F.3d 1123, 1134 (9th Cir. 2019), *cert. denied*, No. 19-1057 (Oct. 13, 2020). An organization cannot "manufacture the [diversion of resources] injury by incurring litigation costs or simply choosing to spend money fixing a problem that otherwise would not affect the organization at all." *Id.* (quoting *La Asociacion de Trabajadores de Lake Forest v. City of Lake Forest*, 624 F.3d 1083, 1088 (9th Cir. 2010)).

Even assuming that the Amended Complaint sufficiently pleads that FDA's approval of Experior

frustrates Plaintiffs' missions, Plaintiffs have not established organizational standing because their Amended Complaint lacks any allegations regarding resource diversion. Plaintiffs make no effort to articulate how, if at all, they have expended financial or other resources in response to Experior's approval. Nor do they argue that they have redirected such resources from other initiatives.

Plaintiffs' failure to allege diversion of resources is fatal to any claim of organizational standing. *See Greenlining Inst. v. Fed. Commc'ns Comm'n*, 802 F. App'x 232, 233–34 (9th Cir. 2020) (no standing for organizations that failed to prove either prior and ongoing diversion of resources, or an "estimate of the resources that will be diverted as a result of the [challenged government] order"); *Citizens for Quality Educ. San Diego v. Barrera*, 333 F. Supp. 3d 1003, 1021 (S.D. Cal. 2018) (no standing where "neither organization allege[d] a diversion of resources" (emphasis omitted)); *Haynie v. Harris*, No. C 10-01255 SI, 2014 WL 899189, at *7 (N.D. Cal. Mar. 4, 2014) (Illston, J.) (no standing where sole allegation of diversion of resources was one organization's "allegations that it paid for the defense of several members," and organizations did "not allege that they have incurred any expenses aside from the litigation costs"), *aff'd*, 658 F. App'x 834 (9th Cir. 2016).

Plaintiffs are likewise unable to secure Article III standing by relying on FDA's denial of Plaintiff ALDF's Petition, or on the alleged deprivation of opportunities to participate in the administrative process. (*See* Am. Compl. ¶¶ 35–36, 3d Claim ¶ 24.) FDA regulations provide broad opportunities for citizens to petition FDA for different types of relief—including through submitting "citizen petitions" and "petitions for stay of action"—and to comment on petitions that are submitted. *See* 21 C.F.R. §§ 10.30, 10.35. But in order to seek review of FDA's handling of the administrative process in federal court, a plaintiff must be able to satisfy the traditional Article III standing elements. *See Klamath Water Users Ass'n v. Fed. Energy Regulatory Comm'n*, 534 F.3d 735, 738 (D.C. Cir. 2008); *Physicians for Integrity in Med. Rsch., Inc. v. Comm'r*, No. CV1108334GAFFMOX, 2012 WL 12882760, at *2 (C.D. Cal. May 23, 2012), *aff'd sub nom. Physicians for Integrity in Med. Rsch., Inc. v. Hamburg*, 556 F. App'x 621 (9th Cir. 2014).

B. Plaintiffs Do Not Have Associational Standing Because Their Members Have Not Suffered Injury In Fact.

To establish associational standing on behalf of their members, an organization "must allege that its members, or any one of them, are suffering immediate or threatened injury as a result of the challenged action of the sort that would make out a justiciable case had the members themselves brought suit." *Hunt*, 432 U.S. at 342–43.

The requirements for injury in fact are familiar: Plaintiffs must allege that their members[1] "suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Spokeo*, 136 S. Ct. at 1548 (quoting *Lujan*, 504 U.S. at 560). "The Supreme Court has repeatedly refused to recognize a generalized grievance against allegedly illegal government conduct as sufficient to confer standing." *Carroll v. Nakatani*, 342 F.3d 934, 940 (9th Cir. 2003).

When the injury has not yet been inflicted, a "threatened injury must be *certainly impending* to constitute injury in fact," for "[a]llegations of *possible* future injury" remain purely conjectural. *Clapper*, 568 U.S. at 409 (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)) (alteration in original); *see also Susan B. Anthony List*, 573 U.S. at 158 (suggesting "substantial risk" remains a valid formulation of the threshold as well (quoting *Clapper*, 568 U.S. at 414 n.5)). In *Clapper*, for example, the Supreme Court determined that the respondents' fears of surveillance did not reflect a "certainly impending" threat sufficient to establish injury in fact. *Id.* at 410, 417.

Although the immediacy requirement is loosened in the context of procedural injury, *Lujan*, 504 U.S. at 572 n.7, "deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing," *Summers v.*

[1] Although the Amended Complaint discusses "members and supporters" of Plaintiff FACT (Am. Compl. ¶ 30; *see also id.* ¶¶ 31–32.), it is not clear that FACT is a membership organization. *See* FACT, IRS 2019 Form 990, at 6 (representing that FACT does not have any members, in response to Part VI, Section A, Question 6), *available at* https://foodanimalconcernstrust.org/financials (last visited Oct. 29, 2020); *see Gordon*, 739 F. App'x at 411 (permitting reliance on material outside of pleadings to resolve factual dispute on jurisdictional challenge). If FACT does not have members, Plaintiffs cannot rely on allegations regarding "supporters" of FACT to establish associational standing, *see Hunt*, 432 U.S. at 342 (describing membership basis for associational standing), and such allegations should be disregarded.

Earth Island Inst., 555 U.S. 488, 496 (2009). Thus, for alleged environmental harms arising from a deprivation of a procedural right, plaintiffs claiming a procedural injury must still allege "a 'geographic nexus' between the individual asserting the claim and the location suffering an environmental impact," *Nuclear Info. & Res. Serv. v. Nuclear Regulatory Comm'n*, 457 F.3d 941, 949–50 (9th Cir. 2006) (quoting *Ashley Creek Phosphate Co. v. Norton*, 420 F.3d 934, 938 (9th Cir. 2005)), *i.e.*, "that they will suffer harm as a result of their proximity to the area where the alleged environmental impact will occur," *id.* at 952.

Here, Plaintiffs have not established that the harms they allege are concrete and particularized and actual or imminent because they do not even allege that Experior is on the market (*see* Am. Compl. ¶ 33.), let alone allege which feedlots will use Experior once it is (*see, e.g.*, *id.* ¶ 26 (alleging their members live "downstream from cattle feedlots that *may* give their cows Experior" (emphasis added)); *id.* ¶ 28 (raising concerns about "the *future* use of Experior by feedlots" (emphasis added)).). Further, they do not adequately establish that they live or recreate in areas likely to be affected by harms they allege. Even for purported environmental harms arising out of Plaintiffs' procedural claim under NEPA, because Plaintiffs "have not alleged with any specificity what geographic areas are most likely to be affected, other than to assert that the [approval] impact[s] [feedlots] nationwide," they have failed to establish a concrete interest in the challenged agency action. *Nuclear Info.*, 457 F.3d at 953.

Grouping by category harms allegedly suffered by Plaintiffs' members, Plaintiffs allege that their members are harmed by FDA's approval of Experior because: (1) Experior *may* contaminate "air and water" in the vicinity of feedlots where Experior *may be* used and allegedly "near" where Plaintiffs' members live or recreate (*see* Am. Compl. ¶¶ 3, 9, 20, 23, 24, 26–28, 30, 74, 79-81, 90, 101–04.); (2) Experior *may* allow industrial farming operations to "greenwash" environmental impacts and accelerate the industry's growth (*see id.* ¶¶ 34, 91–120.); (3) Experior *may* have an impact on Plaintiffs' recreational activities, including wildlife that Plaintiffs' members enjoy watching and/or eating (*see, e.g.*, *id.* ¶¶ 20, 21, 23, 26, 28, 31, 74, 102, 111.); and (4) Experior *may* affect food safety (*see, e.g.*, *id.* ¶¶ 3, 8,

22, 26– 27, 30, 32, 71, 72, 74–75, 101–04, 119.).[2]

Despite Plaintiffs' attempt to make member-specific allegations in their Amended Complaint, their efforts fall short of establishing standing because such harms are speculative. And the allegations that Plaintiffs' members are likely to suffer such harms fail to demonstrate a personalized stake in the outcome of this matter. Indeed, for each of the four categories of alleged harm described above, Plaintiffs fail to show that their members face imminent harm and/or that a geographic nexus exists between their members and any alleged environmental impact. Accordingly, Plaintiffs have not demonstrated that their members sustained an injury in fact, and therefore Plaintiffs lack standing.

1. *Air And Water Contamination*

Plaintiffs allege that their members may be harmed by Experior emanating from feedlots contaminating air and water, including drinking water, near where members live or recreate. (Am. Compl. ¶¶ 19, 20, 23, 24, 26–28, 31.) Plaintiffs do not allege that Experior has caused any such contamination yet. Indeed, they do not even allege that any feedlot has used Experior or allege any basis for identifying which feedlots will use Experior and cause such contamination in the future. Without such information, it is impossible to determine which geographic area(s) may be affected by Experior contamination, and Plaintiffs have thus failed to establish a requisite "geographic nexus" for their claimed injuries. *See Nuclear Info.*, 457 F.3d at 952–53 (holding petitioners did not sustain injury in fact, because they had not pled "with any specificity what geographic areas are most likely to be affected, other than to assert that the regulations impact highways nationwide").

Assuming, *arguendo*, that Plaintiffs had adequately alleged which feedlots were likely to use Experior, their injury allegations would still fall short because they fail to adequately allege their members' proximity to those feedlots. For instance, ALDF claims that "many" of its members "live near,

[2] In addition to these categories of alleged harm, Plaintiffs mention additional generalized harms throughout their complaint: feedlot worker safety concerns (*see* Am. Compl. ¶¶ 3, 8, 70–71, 119); injuries to animals that consume beta-agonists (*see id.* ¶¶ 3, 27, 67–69, 75, 93, 136–39.); exposure to antibiotic-resistant bacteria (*see id.* ¶¶ 85–88, 114–18.); effects of climate change (*see id.* ¶ 108.); and harm to "tourism-dependent communities" (*id.* ¶ 111.). Those adverse impacts, however, are not connected to an alleged injury to any of their members, so they cannot establish standing. *See Lujan*, 504 U.S. at 575 (grievance not specific to plaintiffs is insufficient).

recreate near, and closely monitor [concentrated animal feeding operations ("CAFO")] in their communities" (Am. Compl. ¶ 19.), and the Amended Complaint discusses unnamed individual members purportedly affected by environmental contamination. (*See* Am. Compl. ¶ 23 (recreating near "waterways downstream from cow feedlots in Texas"); ¶ 24 ("lives on the banks of the Mississippi River" in Iowa); ¶ 27 ("lives [in Iowa] adjacent to fields where manure from feedlots is spread); ¶ 28 (recreating in "water downstream from cattle feedlots" and in "conservation areas adjacent to and downstream from cow feedlots"); ¶ 31 ("lives directly on Lake Michigan, a waterway with documented impacts from cattle feedlot pollution" and refers to "feedlots near Lake Michigan").) Yet the Amended Complaint does not define the loose concept of nearness, nor does it suggest the distance that any Experior-induced contamination could be expected to travel.

Even when discussing individual members, Plaintiffs actually say little about the proximity of their members' activities to feedlots. For example, "downstream" can mean an immediately adjacent property or a property miles away, especially on a river as long as the Mississippi. *See* Nat'l Park Serv., *Mississippi River Facts*, https://www.nps.gov/miss/riverfacts.htm (last visited Oct. 29, 2020) (documenting length upwards of 2,300 miles); *see also Ashley Creek Phosphate Co.*, 420 F.3d at 938–39 (no injury in fact for lack of "judicially recognizable geographic nexus" between plaintiff's interest and the affected site 250 miles away). The individual[3] who lives "directly on" Lake Michigan (Am. Compl. ¶ 31.) may live a hundred miles away or even on the other side of the lake from any feedlot using Experior—assuming any feedlots that drain to Lake Michigan actually use Experior at all. Even for members who claim connection to properties "adjacent" to feedlots (Am. Compl. ¶¶ 27–28.), Plaintiffs fail to provide information about the size of the properties affected, the proximity to the property line of any disposal that may lead to contamination, or the distance that any contamination would be reasonably expected to travel. Because Plaintiffs do not clearly plead how "near" their members are to feedlots, how close they would need to be to experience any impacts by contamination from the feedlots, or that any

[3] Plaintiffs allege that this individual is a member of FACT, but as discussed above, if Plaintiffs cannot substantiate that FACT has members, this individual's alleged injuries should not be considered for purposes of standing. *See supra* note 1.

such contamination spill-over would happen near their members, they have not alleged a concrete harm sufficient to establish injury in fact. *See Nuclear Info.*, 457 F.3d at 949–50 (discussing concreteness).

Further, Plaintiffs allege that one member in Idaho "*enjoys visiting* conservation areas *adjacent to*" feedlots (Am. Compl. ¶ 28 (emphasis added).), but absent any indication of when such a visit last took place, or the frequency of such visits, aside from the conclusory and vague allegation of "concrete plans to visit . . . in the future" (*id.*), allegations of harm to this member from the approval of Experior are no more concrete. *See Wilderness Soc., Inc. v. Rey*, 622 F.3d 1251, 1256 (9th Cir. 2010) (rejecting "'some day' general intention to return to the national forests of two geographically large states" as "too vague" because member did "not show that he is likely to encounter an *affected* area of [a specific forest] in his future visits").

It is also highly speculative to claim that Experior will, in fact, contaminate the air and water near feedlots and in turn harm Plaintiffs' members. The Amended Complaint recites a litany of air and water problems allegedly attributable to feedlots in general (*see* Am. Compl. ¶¶ 93–111.), but any such problems predate the use of Experior. Plaintiffs presuppose that cattle farms will mismanage Experior-laden waste, including animal manure and uneaten medicated feed, in a way that would contaminate the environment. (*See id.* ¶¶ 149–50; *see also id.* ¶ 27 (raising concerns of one of Plaintiffs' members who "lives adjacent to fields where manure from feedlots is spread").). Yet Plaintiffs fail to justify their confidence that Experior, even if in use, would result in such effects. (*See, e.g., id.* ¶ 149 (asserting "Experior itself *will* enter the environment through manure" (emphasis added).) Even if Experior were to contaminate the environment, Plaintiffs have not shown that their members would be affected, due to the proximity issues described above.

2. *Industrial Farming Operations*

Plaintiffs claim that their "members and supporters"[4] share the organizations' concern "that

[4] For standing purposes, the Court should disregard allegations here and elsewhere in the Amended Complaint as to Plaintiffs' "supporters," for only their members' concerns could support associational standing. *See Hunt*, 432 U.S. at 342 (describing membership basis for associational standing); *Warth*, 422 U.S. at 511 ("[A]n association may have standing solely as the representative of its members."). For the remainder of this brief, Defendants shall refer solely to the alleged concerns of Plaintiffs' members.

FDA's approval of Experior will further entrench the harmful CAFO industry by making it possible for large feedlots to 'greenwash' their operations by claiming lower emissions of ammonia, which is known to harm human health, rural quality of life, and the environment." (Am. Compl. ¶ 34.) They profess that their members "are also aware that Experior is likely to increase cow herd size and density at feedlots," a trend that allegedly "will encourage construction of new feedlots." (*Id.*) These allegations are insufficient to establish standing because an ideological opposition to expanded feedlots is not cognizable under Article III; instead, they must show an injury that is concrete and particularized and actual or imminent.

Plaintiffs do not begin to establish that such harm is "actual or imminent." They cite no examples of a feedlot that has been expanded or built as a result of Experior's approval; nor do they cite any information that suggests that such activity has even been proposed. Instead, they allege that FDA's approval of Experior *may* lead to the construction of new feedlots. Presumably, this, in turn, *may* lead to harms including contaminated groundwater, surface water, and air pollutants, which *may* harm individuals in the vicinity of these feedlots, some of whom *may* be ALDF or FWW members. Such attenuated allegations do not amount to an "actual" injury or an "imminent" threat, but instead fall within the category of "conjectural" or "hypothetical" harms that do not amount to cognizable injury in fact. *Lujan*, 504 U.S. at 560 (quoting *Whitmore*, 495 U.S. at 155). Plaintiffs have not demonstrated that any member "is *immediately* in danger of sustaining some *direct* injury as the result of the challenged official conduct and the injury or threat of injury is both real and immediate, not conjectural or hypothetical." *Scott v. Pasadena Unified Sch. Dist.*, 306 F.3d 646, 656 (9th Cir. 2002) (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983)).

Further, even under the theory of a deprivation of procedural rights, Plaintiffs must establish a geographic nexus between their members and expanded feedlots. *See Nuclear Info.*, 457 F.3d at 949–50. Their failure to do so deprives them of Article III standing. *See Lujan*, 504 U.S. at 575 ("'generalized grievance[s]' [are] inconsistent with 'the framework of Article III' because 'the impact on [Plaintiffs] is plainly undifferentiated and "common to all members of the public"" (quoting *United States v. Richardson*, 418 U.S. 166, 171, 176–77 (1974))). Although Plaintiffs make general allegations, using

relative terms, that certain of their members live or recreate "near" or "downstream" from CAFOs (*see, e.g.*, Am. Compl. ¶¶ 19, 20, 23, 26, 27, 28, 31) or eat fish caught downstream of CAFOs (*see, e.g.*, Am. Compl. ¶¶ 20, 23), these vague allegations regarding unnamed members do not establish the necessary geographic proximity, nor do they provide enough information for the Court or Defendants to meaningfully investigate them. *See supra* Part I.B.1.

Such attenuated and hypothetical allegations do not establish a certainly impending harm or substantial risk to Plaintiffs' members. *See Susan B. Anthony List*, 573 U.S. at 158; *see also Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4, 19 (D.D.C. 2008) (rejecting pharmacists' standing to challenge FDA approval because their "claim that their risk of legal liability ha[d] increased [was] speculative" absent factual support), *aff'd*, 358 F. App'x 179 (D.C. Cir. 2009) (per curiam).

3. *Outdoor Recreation And Wildlife Observation*

Plaintiffs also allege that Experior will detrimentally impact their members' recreational opportunities, including participating in water activities, observing wildlife, and eating wild fish, based on Experior's anticipated contributions to water pollution and its purported effects on "wildlife in areas downstream from cow feedlots." (Am. Compl. ¶¶ 20, 21, 23–24, 26, 28, 30, 31, 74, 102, 111.) Here again, harm to such interests will constitute an injury in fact only if Plaintiffs establish a "geographical nexus" between their members and the alleged harm. *Nuclear Info.*, 457 F.3d at 952 (explaining that to properly assert that their "aesthetic or recreational interest[s]" have been harmed, "environmental plaintiffs must allege that they will suffer harm by virtue of their geographic proximity to and use of areas that will be affected by the [agency's] policy.") (second alteration in original) (emphasis, citations, and quotation marks omitted)); *see also Lujan*, 504 U.S. at 566 ("[P]laintiff must use the area affected by the challenged activity and not an area roughly 'in the vicinity' of it."); *Tulacz v. Tri-Cty. Metro. Transp. Dist. of Oregon*, No. CIV. 91-1010-JO, 1992 WL 205942, at *4 (D. Or. July 14, 1992) (allegation that plaintiff operated vehicle in affected area not sufficient to establish geographic nexus for purposes of standing).

As with their allegations of environmental impacts discussed above, Plaintiffs do not establish the geographic locations of feedlots that have used or will use Experior. *See supra* Part I.B.1. Nor do they

clearly plead how "near" their recreational interests are to any such feedlots, how close they would need to be to experience any impacts by contamination from the feedlots, or that any such contamination spill-over would happen near their members. (*See* Am. Compl. ¶¶ 20, 21, 23–24, 26, 28, 30–31.) Thus, they have not alleged a concrete harm sufficient to establish injury in fact. For reasons discussed above, such generalized descriptions fail to establish the nexus required for injury in fact. *See supra* Part I.B.1.

4. *Food Safety*

Plaintiffs also fail to establish a cognizable harm based on members' consumption of food, including beef; nor could they. Plaintiffs claim that their members "consume beef purchased from grocery stores and restaurants, which *can be* sourced from feedlots that *will likely* use Experior." (Am. Compl. ¶ 22 (emphasis added); *see also* ¶¶ 3, 8, 26, 30, 32, 71–72, 75.) But these allegations are wholly speculative and lack a connection between the members and the sources of beef.

Plaintiffs do not claim that beef currently on the market comes from feedlots that use Experior. Nor is there any suggestion *when* cows raised with Experior could reach the market, *where* that beef would be available to grocery stores or restaurants, or *how likely* those grocery stores and restaurants are to select that beef. Plaintiffs merely speculate about "*possible* future injury" to their members, which does not qualify as a "certainly impending" harm. *Clapper*, 568 U.S. at 409. Nor do Plaintiffs' members face a "substantial risk of harm" "in light of the attenuated chain of inferences necessary to find harm here." *Id.* at 414 n.5.

Moreover, nowhere do Plaintiffs provide specific allegations about how Experior has or imminently will harm human health through beef consumption. Instead, Plaintiffs allege that their members have "concerns," "fear[s]," or "skepticism of the safety of beef." (Am. Compl. ¶¶ 22–24.) But unsubstantiated fears do not give rise to Article III standing. *Clapper*, 568 U.S. at 420 (denying standing where plaintiffs "present no concrete evidence to substantiate their fears, but instead rest on mere conjecture"). In toxic exposure cases, "Plaintiffs must plead a credible or substantial threat to their health or that of their children to establish their standing to bring suit." *Herrington v. Johnson & Johnson Consumer Cos.*, No. C 09-1597 CW, 2010 WL 3448531, at *3–4 (N.D. Cal. Sept. 1, 2010) (Wilken, J.) (dismissing for lack of standing claim based on alleged injury from exposure to "probable human

carcinogens" as "too speculative and uncertain to confer Article III standing"); *see also, e.g.*, *Boysen v. Walgreen Co.*, No. C 11-06262 SI, 2012 WL 2953069, at *7 (N.D. Cal. July 19, 2012) (Illston, J.) (same for lead and arsenic); *In re Fruit Juice Prods. Mktg. & Sales Practices Litig.*, 831 F. Supp. 2d 507, 512 (D. Mass. 2011) (same for lead); *Koronthaly v. L'Oreal USA, Inc.*, 374 F. App'x 257 (3d Cir. 2010), *aff'g* No. 07–CV–5588, 2008 WL 2938045 (D.N.J. July 29, 2008) (same); *Frye v. L'Oreal USA, Inc.*, 583 F. Supp. 2d 954 (N.D. Ill. 2008) (same); *cf. Backus v. Gen. Mills, Inc.*, 122 F. Supp. 3d 909, 921–23 (N.D. Cal. 2015) (Henderson, J.) (rejecting argument that alleged impact of trans fats on disease risk supported standing, where plaintiff "fail[ed] to allege a *substantially* increased risk" under *Clapper* (emphasis added)).

Judge Wilken's decision in *Herrington* is instructive. There, plaintiffs alleged an injury based on exposure to "probable human carcinogens," while failing to allege (1) that the substances were "in fact carcinogenic for humans" or (2) "that the amounts of the substances" to which they had been exposed "have caused harm or create a credible or substantial risk of harm." *Herrington*, 2010 WL 3448531, at *3. Judge Wilken dismissed for lack of standing, reasoning that allegations that the substances "*may* be carcinogenic for humans," and "that there *could* be no safe levels for exposure to carcinogens" were "too attenuated and not sufficiently imminent to confer Article III standing." *Id.*

So too here. Plaintiffs do not allege that Experior is actually harmful to humans, let alone that the amounts to which they might be exposed will cause "harm or create a credible or substantial risk of harm." *Id.* Faced with strict FDA regulations restricting Experior residues in cattle liver tissue to just 10 parts per billion—the same standard applicable to arsenic in drinking water[5]—Plaintiffs provide no specific allegations about how treating cattle with Experior will lead to significant human health risks. They neither allege that such residues will harm human health, nor provide any basis—let alone a credible basis—for believing that food from cows treated with Experior would exceed those residue levels. *Cf. In re Fruit Juice Prods. Mktg.*, 831 F. Supp. 2d at 511–12 (dismissing "risk of future harm" claim as "too

[5] *Compare* 21 C.F.R. § 556.370 (b)(1) (setting tolerance for lubabegron [Experior] residues in cattle liver at 10 parts per billion (ppb)), *with* 40 C.F.R. § 141.62(b)(16) (setting the acceptable level of arsenic in drinking water at 10 ppb or 0.01 mg/L), *and* 21 C.F.R. § 165.110(b)(4)(iii)(A) (same for bottled water). (*See also* Am. Compl. ¶ 29 (professing FACT's ancillary concern with arsenic).)

speculative," absent any allegation "that the levels of lead in Defendants' products violated any FDA standards" or inflicted any injuries on consumers). Without more specific allegations, Plaintiffs have established nothing more than a "highly speculative fear" that "relies on a highly attenuated chain of possibilities," *Clapper*, 568 U.S. at 410, *viz.* that Experior *may* be used to treat cows from which food is derived that *may* be purchased by their members who *may* be harmed by eating such food through some *unexplained* cause in which miniscule residues *could* cause adverse human health consequences.

Plaintiffs attempt to equate the anticipated effects of Experior on human health with allegedly harmful effects of other beta-agonist drugs.[6] (*See* Am. Compl. ¶¶ 63–75 (arguing that beta-agonists increase the likelihood of injury to feedlot workers and food consumers).) That linkage is conclusory. (*See, e.g., id.* ¶ 70 (taking generic preceding description of beta-agonist harms as support for this premise: "Because Experior negatively influences animal behavior, it corresponds to an increased risk to humans who work with them.").) But even assuming that Experior has the same effect on food safety as other beta-agonists, Plaintiffs do not point to a single member who has been harmed, or faces imminent harm, as a result of eating food derived from cattle treated with beta-agonists. One member is concerned based on "witness[ing]" pigs' response to other beta-agonists[7] (*id.* ¶ 27.), but that does not establish imminent likelihood of injury from consuming food derived from cows treated with Experior. Although some members allegedly propose altering their purchasing or consuming habits as a result of FDA's approval (*id.* ¶¶ 22–24, 26, 27, 30, 32.), it is unclear why they have not already done so, in response to other beta-

[6] Similarly, the Amended Complaint draws unfounded conclusions about Experior's likely environmental impact based on the alleged impact of other beta-agonists. (*See* Am. Compl. ¶ 74.) Plaintiffs go so far as to claim that Experior "persists in the environment" for a long time based on its half-life (*id.*), but Plaintiffs offer no support for the intimation that Experior already can be found in the environment.

[7] Any concerns about feedlot worker injury from animals fed beta-agonists (*see* Am. Compl. ¶¶ 3, 8, 70, 71, 119) do not establish associational standing for Plaintiffs, who have not alleged that any of their members currently work on feedlots. Rather, "one FWW member . . . has experience working on a feedlot," while others "work . . . near and downstream from cattle feedlots." *Id.* ¶¶ 26, 27. They have not alleged that working near or downstream from cattle feedlots—nor working on a feedlot in the past—expose workers to injury from animals fed Experior or any other beta-agonists.

agonists on the market.[8] For these reasons, the allegation that FDA's approval of Experior renders Plaintiffs' members food derived from treated cattle unsafe—or raises concerns sufficient to generate changes in consumer behavior—is purely hypothetical.

Further, many of the allegations about the harmful effects of beta-agonists are highly speculative. For example, Plaintiffs claim that beta-agonists may render cows non-ambulatory, which may in turn cause these cows to pick up pathogens from the dirt and "carry [them] into the slaughterhouse." (Am. Compl. ¶¶ 70, 75.) But any such pathogens could have an impact on food purchased by Plaintiffs' members only if cows that cannot walk nevertheless pass through the meat inspection process without detection. A robust statutory and regulatory regime minimizes risk of that happening. *See* 21 U.S.C. § 603(a) (establishing pre-slaughter inspection of animals, with those that "show symptoms of disease" to "be set apart"); 9 C.F.R. § 309.2 (requiring disposal of "seriously crippled animals and non-ambulatory disabled livestock"). Plaintiffs plead no facts demonstrating that such a scenario is likely, much less that it poses a certainly impending harm to Plaintiffs' members.

* * *

In short, neither Plaintiffs nor their members are cognizably harmed by FDA's approval of Experior. This action should therefore be dismissed for lack of standing.

II. Plaintiffs Fail To Adequately Allege That Any Purported Harms Were Caused By FDA's Approval Of Experior.

Even if the Plaintiffs plead a plausible injury in fact (they do not), the Court should dismiss their claims for failure to establish the second prong of the standing inquiry. Plaintiffs have not fairly traced their asserted harms to FDA's approval of Experior.

"The line of causation between the defendant's action and the plaintiff's harm must be more than attenuated." *Wash. Envtl. Council v. Bellon*, 732 F.3d 1131, 1141 (9th Cir. 2013) (quoting *Native Vill.*

[8] Another member allegedly "fears that FDA's approval of Experior may financially hurt his business of selling natural drug-free beef, as he believes that increased drug use on cattle feedlots perpetuates a growing public perception that all beef is unsafe to eat and that the labeling of all beef cannot be fully trusted." (Am. Compl. ¶ 31.) This is wholly speculative: there are no allegations that approval of other beta-agonists has had such an effect on the member's business, nor is there any suggestion of whether or when such feared changes would affect his business.

of Kivalina v. ExxonMobil Corp., 696 F.3d 849, 867 (9th Cir. 2012) (Pro, J., concurring)). Although a causal inference may justifiably require multiple steps, those steps do not satisfy the pleading threshold if they are "hypothetical or tenuous." *Id.* at 1141–42 (quoting *Native Vill. of Kivalina*, 696 F.3d at 867 (Pro, J., concurring)). "[W]here the causal chain involves numerous third parties whose independent decisions collectively have a significant effect on plaintiffs' injuries, . . . the causal chain is too weak to support standing." *Id.* at 1142 (quoting *Native Vill. of Kivalina*, 696 F.3d at 867 (Pro, J., concurring)).

In this case, Plaintiffs attempt to draw a causal inference between FDA approval of Experior and their asserted harms—but that approval has no fairly traceable relationship to the purported harms. Those harms are instead attributable to third-party feedlot practices or other drugs. Nor does Plaintiffs' members' attempt to manufacture causation by inflicting harms on themselves provide sufficient basis for standing.

A. Many Of The Alleged Harms Are Attributable To Existing Third-Party Feedlot Practices.

The Amended Complaint includes a lengthy section on the purported harms of feedlots generally, including air and water pollution, greenhouse gas emissions, and foodborne illnesses. (*See* Am. Compl. ¶¶ 91–120.) This section is presumably intended to substantiate the harms allegedly suffered by Plaintiffs. *See supra* Part I.B. (*See also* Am. Compl. ¶¶ 19-34.) Plaintiffs, however, do not link these allegations to Experior. Instead, they claim that feedlots—which they do not allege are using Experior—are the source of each of these harms. (*See, e.g.*, *id.* ¶ 96 ("CAFOs are one of the largest sources of water pollution in the country."); ¶ 101 ("CAFOs must store [animal] waste for long periods of time . . . . Unlined or inadequately lined manure storage lagoons can contaminate communities' well water if the manure leaks through the soil into aquifers below."); ¶ 103 ("Nitrate contamination from cow manure can also cause downstream communities to bear significant costs to treat municipal drinking water."); ¶ 105 ("The concentration of animals at CAFOs also produces air pollutants . . . ."); ¶ 108 ("CAFOs and CAFO waste disposal also release the powerful greenhouse gases methane and nitrous oxide."); ¶¶ 113–14, 117 ("[U]se of antibiotics at CAFOs leads to the development and spread of antibiotic-resistant bacteria . . . . [which] are capable of transferring to humans . . . . Upon human exposure, the resistant

bacteria can colonize the human gut and cause illnesses resistant to clinically important antibiotics."). Plaintiffs do not even allege that these third-party feedlots use Experior, let alone that such use is somehow related to the list of harms they associate with feedlots.

B. Many of the Alleged Harms Are Not Attributable to Experior Specifically.

Causation is also lacking because Plaintiffs fail to tether their alleged harms to Experior as opposed to other beta-agonists.[9] In particular, the allegations about air and water contamination, recreational harms, and food safety concerns relate to harms caused by beta-agonists in general but have no specific or unique association with Experior.

Plaintiffs' claims of contamination to their members' air and water are based on information related to ractopamine, which is a different drug than Experior and indeed a different subtype of beta-agonist. (*See* Am. Compl. ¶ 74 (explaining how ractopamine allegedly "contaminates ground and surface waters"); *id.* ¶ 139 (identifying ractopamine as a beta-2 drug).) Although Plaintiffs make brief reference to Experior's half-life, suggesting that it will generate similar harms because of its persistence, they simply have not shown that FDA's approval of Experior has caused the kinds of effects they describe.

It is also not clear how any recreational interests are negatively influenced by Experior's approval. Plaintiffs acknowledge that beta-agonists are a staple of the industrial meat processing industry (Am. Compl. ¶ 64.), and any number of those drugs could have the alleged effects on recreation that concern Plaintiffs' members (*see id.* ¶ 111 (asserting that CAFOs create haze causing "significant losses of public enjoyment of wildlife and wilderness areas").).

Similarly, regarding food safety, the Amended Complaint asserts that beta-agonist drugs as a

[9] Plaintiffs include allegations about harms ostensibly caused by other new animal drugs approved by FDA, including new animal drugs that include Experior along with other active ingredients, such as monensin and tylosin. (See Am. Compl. ¶¶ 12, 76–90, 131.) Defendants note that Plaintiffs have not submitted any petition to FDA with respect to its approvals of these other drugs. Thus, Plaintiffs plainly have not exhausted administrative remedies for any challenge to these approvals. Nor, for reasons set out in this brief, have Plaintiffs established injury in fact, causation, or redressability as to any alleged harms caused by these drugs, so any such harms do not confer Article III standing in this litigation.

general category can cause health issues in cattle (Am. Compl. ¶¶ 66–70), and are detrimental to consumers with "compromised cardiovascular systems" (*id.* ¶ 72). Plaintiffs further claim that human "expos[ure] to or consum[ption]" of food derived from animals treated with beta-agonists has led to "nausea, dizziness, respiratory issues, and other serious medical conditions." (*Id.* ¶ 71). But Plaintiffs do not allege that any of these harms have been attributed to Experior specifically, or even to the subtype of beta-agonists to which Experior belongs.[10] Nor can they explain how any alleged harms that may occur would be traced to Experior, as opposed to other causes, including other beta-agonists that Plaintiffs admit are administered to food-producing animals. (*See id.* ¶ 64.); *cf. Bellon*, 732 F.3d at 1142–43 (rejecting at summary judgment stage the sufficiency of "vague, conclusory statements" that agency non-action causes greenhouse gas emissions).

At bottom, Plaintiffs do not allege that Experior is used on feedlots, so all of the harms allegedly attributable to beta-agonists stem from drugs other than Experior. FDA's Experior approval could not conceivably have caused those harms.

C. The Alleged Harms Would Be Caused, If At All, By Third Parties, Not Experior.

Plaintiffs' alleged injuries also cannot be "fairly traced" to FDA's Experior approval because any of the injuries alleged would occur only if third parties, such as feedlot operators, take (or fail to take) independent action. *See Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41–42 (1976) (reciting Article III restriction to "redress[ing] injury that fairly can be traced to the challenged action of the defendant, and not injury that results from the independent action of some third party not before the court").

For example, increasingly dense feedlots would generate increased environmental contamination

[10] Although Plaintiffs state that Experior is a beta 3-phenethanolamine adrenergic agonist/antagonist (Am. Compl. ¶ 63. *But see id.* ¶ 139 (claiming it also has "some" beta 2 "activity").), their Amended Complaint discusses the effects of beta-agonists generally (including drugs that activate in the beta-1 and beta-2 subtype receptors), without distinguishing among the three classes of beta-adrenergic receptors. It is inappropriate to generalize effects of beta-agonists generally to Experior specifically. Experior is the first new animal drug that FDA's Center for Veterinary Medicine has approved that specifically activates the beta-3 receptor. It is not reasonable to lump Experior in with other beta-agonists that activate the beta-1 and beta-2 receptors and assume they will behave the same way. Plaintiffs' overly-inclusive approach to invoking scientific research regarding other beta-agonists (*id.* ¶ 66) has the improper effect of conflating the findings of studies done on distinct types of beta-agonist drugs.

only if feedlot operators, or other decision-makers within the industrial farming industry, decide to administer Experior to their cattle, and then based on decreased ammonia emissions, choose to expand operations without taking steps to reduce adverse environmental effects from such expansion. This strained chain of logic relies heavily on the actions of third parties, but the Amended Complaint lacks any concrete allegations that such actions have been or will be taken in the immediate future. (*See* Am. Compl. ¶ 34 (alleging only that Experior's approval "will encourage construction of new feedlots" because Experior "is likely to increase cow herd size and density at feedlots"); *see also id.* ¶ 106 ("Experior also enables CAFO operators to confine more cows per feedlot while touting lower ammonia emissions . . . .").)

Such a causal chain of events, which relies on speculative assertions about the behavior of independent third parties, is inadequate to establish the second prong of the standing inquiry. *Bellon*, 732 F.3d at 1144 (where "a multitude of independent third parties are responsible for the changes contributing to Plaintiffs' injuries, the causal chain is too tenuous to support standing"); *Ctr. for Biological Diversity v. U.S. Dep't of Interior*, 563 F.3d 466, 479 (D.C. Cir. 2009) (no standing where petitioner's argument that government action caused climate change "rel[ied] on the speculation that various different groups of actors not present in this case . . . might act in a certain way in the future").

Similarly, concerns about foodborne illness due to animals that Experior may render non-ambulatory or otherwise harm (Am. Compl. ¶¶ 70, 75, 119), would result, if at all, only from a series of hypothetical actions far removed from FDA's Experior approval. First, a feedlot operator would need to hold cattle under stress conditions that make them "more susceptible to pathogens," (*id.* ¶ 75), and to fail to take precautions against infection by pathogens. The operator would then have to overlook the disease or disability of such animals and take them to slaughter, while the animals would then need to escape detection during the federally regulated inspection process. *See supra* Part I.B.4. (describing speculative nature of that harm). Such hypothetical steps, all dependent on the actions of multiple third parties, cannot reasonably be attributed to FDA's Experior approval.

Nor can FDA's approval be cited as the cause of any above-tolerance residues identified in the edible tissues of treated animals at some future date. Independent feedlot operators would need to choose

to administer Experior, and to do so in a manner that ignores established administration and disposal requirements. *See supra* Part I.B.4. Such a causal chain is too attenuated to support Article III standing.

D. Self-Inflicted Harms Are Not Fairly Traceable To FDA's Approval.

Plaintiffs also rely on their members' alleged plans to alter food consumption habits or forego recreation specifically in response to Experior. *E.g.*, Am. Compl. ¶¶ 22–24, 26–28, 31. But those anticipated harms are merely "self-inflicted injuries [that] are not fairly traceable to the Government's [challenged] activities." *Clapper*, 568 U.S. at 418 (deciding costs incurred to address surveillance fears that were not injury in fact were not fairly traceable). Plaintiffs' members may change their routines, but they "cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending." *Id.* at 416; *see also Or. Prescription Drug Monitoring Program v. U.S. Drug Enf't Admin.*, 860 F.3d 1228, 1235 (9th Cir. 2017) (relying on *Clapper* to reject standing for intervenors who were *not* subject to an imminent threat but claimed that government action "causes them psychological distress and *could change their future behavior* in seeking medical treatment" (emphasis added)); *Radich v. Guerrero*, 729 F. App'x 623, 624 (9th Cir. 2018) (organization did not sustain injury in fact based on claim that order would require it to "install metal detectors in schools or hire security guards" as a precaution, when it was under no legal obligation to do so).

Here, the members' anticipatory changes in food consumption or in recreation are not fairly traceable to a certainly impending threat posed by Experior. They are instead attributable primarily to the members' own choices and, to a lesser extent, to beta-agonists in general, or the actions of third-party feedlot operators. Accordingly, they do not establish standing.

III. The Amended Complaint Fails To Allege That A Favorable Decision Would Redress Plaintiffs' Asserted Harms.

Based on alleged violations of the FDCA, NEPA, and the APA, Plaintiffs seek declaratory relief, vacatur of Experior's approval, and an injunction barring Experior's use. (Am. Compl. at 38.) But because all of the complained-of harms are fairly traceable to sources other than Experior's approval, Plaintiffs have not shown that it is "'likely,' as opposed to merely 'speculative,' that the injury will be

'redressed'" by the proposed relief. *Lujan*, 504 U.S. at 561 (quoting *Simon*, 426 U.S. at 38).

To survive a motion to dismiss on the issue of redressability, a plaintiff "must allege facts from which it reasonably could be inferred that, absent the [challenged action], there is a substantial probability . . . that, if the court affords the relief requested, the asserted [injury] of [the plaintiff] will be removed." *Warth*, 422 U.S. at 504; *see also Juliana v. United States*, 947 F.3d 1159, 1170 (9th Cir. 2020) ("Redress need not be guaranteed, but it must be more than 'merely speculative.'" (quoting *M.S. v. Brown*, 902 F.3d 1076, 1083 (9th Cir. 2018)). This is a particularly high hurdle where the challenged action consists of government regulation of third-party activities. *See Lujan*, 504 U.S. at 561–62. Even if a plaintiff can show that government action caused harm, it still must establish that reversing the government action would move third parties in a way that resolves the harm. *See id.*; *Levine v. Vilsack*, 587 F.3d 986, 992–93, 997 (9th Cir. 2009) (remanding for dismissal an action asserting that certain poultry should be covered by the Humane Methods of Slaughter Act, where plaintiffs' redressability allegations relied upon the Secretary of Agriculture's addition of animals to the list of protected species under a separate statute, and plaintiffs' allegations that the Secretary would do so and that resulting regulations would make poultry slaughter more humane were "conclusory and speculative").

At the threshold, Plaintiffs have not alleged how their request for declaratory relief—standing alone—would redress their grievances. Plaintiffs instead seem to rely on the other relief they requested for standing purposes. *See Juliana*, 947 F.3d at 1170 ("A declaration, although undoubtedly likely to benefit the plaintiffs psychologically, is unlikely by itself to remediate their alleged injuries absent further court action.").

But Plaintiffs fare no better in their request for vacatur of FDA's approval of Experior and an injunction against its use. They have not pled how third-party feedlots and other beta-agonists would be affected by vacatur and an injunction limited to Experior. The injuries they attribute to feedlots pre-date the approval of Experior (*see, e.g.*, Am. Compl. ¶¶ 103–04 (citing 2014 and 2017 examples)), or at least its use on feedlots, given that Plaintiffs have not alleged that Experior is used on feedlots. And Plaintiffs recognize that other beta-agonists are already on the market (including ractopamine, *see id.* ¶¶ 73–74, 139), but fail to allege that withdrawal of Experior will have any impact on the availability or use of these

other drugs. The Amended Complaint contains no allegations that if Experior's approval is withdrawn, injuries induced by feedlots or other beta-agonists would disappear.

Similarly, Plaintiffs offer nothing to suggest that, upon withdrawal of Experior's approval, independent third parties, such as feedlot operators, would change their current practices to remedy alleged harms that pre-date Experior's introduction to the market. And any precautions previously taken by Plaintiffs' members to address harms induced by feedlots and other beta-agonists would still apply. *Cf. Clapper*, 568 U.S. at 417 ("[E]ven before [the challenged statute] was enacted, [respondents] had a similar incentive to engage in many of the countermeasures that they are now taking."). Nor would any members' self-inflicted "harms" in anticipation of Experior specifically be redressed by vacatur of its approval.

For these reasons, Plaintiffs cannot plausibly claim that withdrawal of Experior's approval will provide redress for the harms they identify.[11] Any allegations to the contrary need not be accepted at face value, because this Court's obligation "to take a plaintiff at its word at [the motion to dismiss] stage in connection with Article III standing issues is primarily directed at the injury in fact and causation issues, *not redressability*." *Levine*, 587 F.3d at 996–97 (emphasis added). All of Plaintiffs' claims should therefore be dismissed for failure to establish the third prong of Article III standing. *See Allen v. Wright*, 468 U.S. 737, 758 (1984) (holding parents lacked standing to challenge IRS regulations granting tax exemption to racially discriminatory schools because "it is entirely speculative" whether withdrawing the exemption "would have a significant impact on the racial composition of the public schools"), *abrogated on other grounds by Lexmark Int'l Inc. v. Static Control Components, Inc.*, 572 U.S. 118 (2014); *Juliana*, 947 F.3d at 1164, 1170–71 (dismissing on redressability grounds based in part on recognition that enjoining the government's challenged environmental actions would not "suffice to stop catastrophic

[11] Plaintiffs also briefly claim that a proper FDA review of Experior, or a Court-ordered vacatur of its prior action, would facilitate redress by "providing them with accurate data on the risks that Experior poses." Am. Compl. ¶ 36. But this redress argument masks a fundamental flaw in the presumed injury: Plaintiffs are not allowed to simply "reframe[] every procedural deprivation in terms of informational loss." *Wilderness Soc., Inc.*, 622 F.3d at 1260 (recognizing that some "concrete and particular" interest must be harmed apart from the informational loss). Because Plaintiffs have not identified a concrete interest harmed by any lack of information, that basis for redress fails.

climate change or even ameliorate [plaintiffs'] injuries"); *HomeAway Inc. v. City & Cty. of San Francisco*, No. 14-CV-04859-JCS, 2015 WL 367121, at *13 (N.D. Cal. Jan. 27, 2015) (Spero, M.J.) (dismissing relevant portion of complaint for failure to establish redressability, for "[n]either a declaration nor an injunction *as to* [*the challenged government action*] would alter the effect of *preexisting* municipal code provisions").

CONCLUSION

Plaintiffs have identified a variety of alleged harms from feedlots, other beta-agonists, and the actions of the industrial farming industry. Whatever the merits of those allegations, they do not help Plaintiffs to establish standing in this case.

Neither Plaintiffs nor their members have been harmed by FDA's approval of Experior, nor do they sufficiently allege that its approval will harm them in the immediate future. Even if the Court were to discern an injury in fact (it should not), that injury would stem from causes other than Experior. As such, granting Plaintiffs' requested relief—issuing declaratory judgments, vacating Experior's approval, and enjoining its use—would not redress the alleged environmental injuries to human health and welfare identified in the Amended Complaint. All of the claims in the Amended Complaint should be dismissed for lack of Article III standing.

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Respectfully Submitted,

JEFFREY BOSSERT CLARK
Acting Assistant Attorney General

DANIEL J. FEITH
Deputy Assistant Attorney General

GUSTAV W. EYLER
Director

HILARY K. PERKINS
Assistant Director

/s/ Jonathan E. Amgott
JONATHAN E. AMGOTT
Trial Attorney
Consumer Protection Branch

U.S. Department of Justice
P.O. Box 386
Washington, DC 20044-0386
Telephone: 202-532-5025
Facsimile: 202-514-8742
E-mail: Jonathan.E.Amgott@usdoj.gov
D.C. Bar No. 1031947

PAUL E. SALAMANCA
Deputy Assistant Attorney General
United States Department of Justice
Environment and Natural Resources Div.

/s/ Michael S. Sawyer
MICHAEL S. SAWYER
Trial Attorney
Natural Resources Section
P.O. Box 7611 Washington, D.C. 20044
202-514-5273 || 202-305-0506 (fax)
Michael.Sawyer@usdoj.gov

Attorneys for Federal Defendants

Of Counsel:

ROBERT P. CHARROW
General Counsel

STACY CLINE AMIN
Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

ANNAMARIE KEMPIC
Deputy Chief Counsel for Litigation

MICHAEL HELBING
Associate Chief Counsel for Enforcement
United States Food and Drug Administration
Office of the Chief Counsel
White Oak 31, Room 4421A
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Telephone: (240) 402-6165

ATTESTATION

Pursuant to Local Rule 5-1(i)(3), as the ECF user whose user ID and password are being used in the electronic filing of this document, I attest that I file with the concurrence of the other signatory of this document.

/s/ Jonathan E. Amgott

Jonathan E. Amgott

THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

ANIMAL LEGAL DEFENSE FUND, FOOD & WATER WATCH, and FOOD ANIMAL CONCERNS TRUST,

Plaintiffs,

v.

ALEX AZAR, Secretary of the United States Department of Health and Human Services; STEPHEN HAHN, Commissioner of the United States Food and Drug Administration; and UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendants,

and

ELANCO ANIMAL HEALTH,

Intervenor-Defendant.

No. 3:20-CV-03703-RS

[PROPOSED] ORDER

Having considered Defendants' Motion to Dismiss, and any opposition, reply, and oral argument presented, IT IS HEREBY ORDERED that this action is DISMISSED.

IT IS SO ORDERED.

Dated: _____

_____

RICHARD SEEBORG
UNITED STATES DISTRICT JUDGE